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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Warne et al.
SERIAL NUMBER: 10/663,264 EXAMINER: Bruce D. Hissong
FILING DATE: September 16, 2003 ART UNIT: 1646
FOR: Delayed release formulations for oral administration of a polypeptide therapeutic agent and methods of using same

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Declaration of Nicholas W. Warne

I, Nicholas P. Warne, Ph.D., declare and state:

1. I am a co-inventor of the subject matter described and claimed in United States Patent Application Serial No. 10/663,264, filed September 16, 2003, entitled "Delayed release formulations for oral administration of a polypeptide therapeutic agent and methods of using same". I am also an employee of Wyeth, the assignee of the above-referenced application.
2. I have read the publication by Greenwood et al., "Recombinant Human Interleukin-11 Restores Smooth Muscle Cell Function in the Jejunum and Colon of Human Leukocyte Antigen-B27 Rats with Intestinal Inflammation" J. Pharmacol. Exp. Therapeutics 299:58-66, 2001 ("Greenwood Publication"). The authors of the Greenwood publication include Beverley Greenwood-Van Meerveld and Kalina Venkova of the Oklahoma Foundation for Digestive Research Basic Sciences Laboratories and Veteran Affairs Medical Center, Oklahoma City Oklahoma (the "Greenwood Group"), along with James C. Keith, who is a colleague of mine at Wyeth.
3. The Greenwood Publication describes the effect of oral treatment with recombinant human IL-11 oral formulations on rat model models of intestinal mucosal injury.

4. The IL-11 formulations used in the Greenwood Publication were developed by my research group and supplied to the authors of the Greenwood Group by Wyeth under a work-for-hire agreement to test the oral-IL-11 formulations in the rat modal. Two coauthors of the Greenwood Publication--Beverley Greenwood-Van Meerveld and Kalina Venkova-- were members of the Greenwood Group and were doing work under the direction and supervision of me or my Wyeth colleague James Keith, the remaining co-author on the Greenwood Publication. While Mr. Keith was involved in coordinating the testing of the formulations, he was not involved in developing the presently claimed compositions or methods of using the compositions.

5. I further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.

Nicholas W. Warne
Nicholas W. Warne

15 December 2006

Date